



JUN 24 2004

Ms. Jill Bunn  
Technical Manager  
Arkopharma LLC  
22 N. Main Street  
Newport, New Hampshire 03773

Dear Ms. Bunn:

This is in response to your letter of April 2, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the following statement will be made for the product **Health From The Sun ThermoPower CLA with Oolong Tea**:

“[H]elps maintain healthy blood sugar levels.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, a claim that does not establish that the claim is about blood glucose levels that are already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood glucose but does not also include a statement about it being intended to affect blood glucose levels that are already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for

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use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal line extending to the right.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

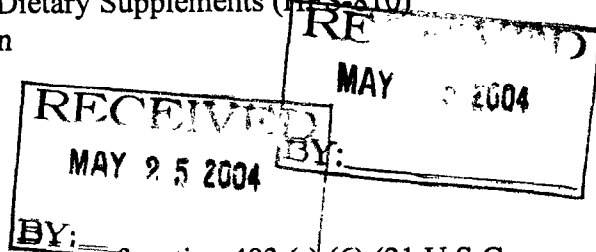
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE240

April 2, 2004

Food and Drug Administration  
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, D.C. 20204



Dear Sirs:

Notice is hereby given pursuant to the requirements of section ~~403 (r)~~ (6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Arkopharma LLC, 22N. Main Street. Newport, NH 03773, within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the label:

Text of Claims:


1. Synergistic fusion of top quality, all-natural ingredients that helps to improve muscle mass while burning fat.
2. Lean For Less ThermoPower CLA with Oolong Tea is the optimal fitness tool for safely toning and sculpting the body, regardless of your fitness level.
3. Conjugated Linoleic Acid, or CLA, is a potent regulator of body composition.
4. This unique combination of CLA and the thermogenic herb, Oolong Tea, will help increase metabolic expenditure without increasing heart rate.
5. High in antioxidants for increased immune support, helps maintain healthy blood sugar levels.

Name of Ingredients Subject to Claim: Modified sunflower and safflower oil, oolong tea extract.

Name of the Supplement: Health From The Sun ThermoPower CLA with Oolong Tea

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma LLC has substantiation that the statement is truthful and not misleading.

Sincerely,

  
Jill Bunn  
Technical Manager

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